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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,345	04/06/2001	Jean-Claude Chermann	065691-0216	4575

22428 7590 07/14/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">09/827,345</p>	<p>Applicant(s)</p> <p align="center">CHERMANN ET AL.</p>	
	<p>Examiner</p> <p align="center">Myron G. Hill</p>	<p>Art Unit</p> <p align="center">1648</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26- 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26- 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendment filed 14 May 2003.

Claims 26- 30 are pending.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26- 30 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the term "cryptic epitope" on page 3, lines 21- 37 is defined. In lines 23- 25, it is not clear how the immune response is defined in that the epitope is hidden and recognized as foreign by the immune system? From this definition it is not clear what function or properties the antibody has that recognizes the cryptic epitope. In claims 28 and 29, it is not clear what the metes and bounds of "at risk of an HIV infection." On page 19, top part, samples from patients who do not progress are disclosed but they are clearly infected because they are seropositive. Or is it meant that a never-exposed-to-HIV individual can be tested to determine if they will become HIV infected?

These rejections are withdrawn in light of explanations and amendments to the claims.

Claim Rejections - 35 USC § 101

Claims 26 and 27 are rejected under 35 U.S.C. 101 because they read on a product of nature. Human beings that contain the antibody are encompassed by the claims.

The rejection is moot in light of the amendment, the antibodies are now "isolated".

Rejections Maintained

Claim Rejections - 35 USC § 112

Claim 28 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is drawn to a method of diagnosing a patient as having HIV by detecting the presence of a cryptic epitope in a subject with the antibody of claim 26. The claim was rejected in part to reading on detecting this epitope in urine.

Applicant argues that the method is drawn to a method of detecting beta-2-microglobulin (B-2-M) in serum samples.

The arguments have been fully considered and not found persuasive.

The claim is not limited to detecting the epitope in serum and still reads on detecting in urine because the urine is in the subject and meets the limitation of the claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Liabeuf in light of Harlow, and NCBI, for reasons set forth in the previous Office action, page 5.

Applicant argues that Liabeuf does not disclose the specific limitations of the claim. These limitations include an antibody that binds to at least one isolated Beta 2-microglobulin (B-2-M) cryptic epitope which has 15 or less amino acids and comprises a sequence Pro-Lys-Ile (PKI).

The arguments have been fully considered and not found persuasive.

The claims are directed to an antibody that binds a B-2-M cryptic epitope, the epitope has 15 or less amino acids and comprises an amino acid sequence Pro-Lys-Ile (PKI).

The claim reads on any B-2-M sequence that contains PKI somewhere in it. It is notoriously well known in the art that antibodies bind to epitopes. Harlow was provided as evidence that antibodies bind to epitopes of 6 or more amino acid residues and the

NCBI sequence of B-2-M was provided to show that the molecule that the antibody of Liabeuf binds to contains the sequence PKI.

Supporting references may be provided to show inherent qualities of the prior art antibodies. The following is an excerpt from the M.P.E.P (8th Edition):

2131.01 Multiple Reference - 2100 Patentability

Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

- Show that a characteristic not disclosed in the reference is inherent.

Extra Reference or Evidence Can Be Used To Show an Inherent Characteristic of the Thing Taught by the Primary Reference

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical

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ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

The inclusion of the Harlow, and NCBI references in the statement of the rejection is not a new ground of rejection as the body of the previous rejection clearly indicates the use made of these references in support of anticipation by Liabeuf.

Liabeuf discloses an antibody that binds to a cryptic (hidden) epitope on B2- M.

Conclusion

No claims are allowed.

Le Contel is cited as art if interest. Le Contel discloses further binding characteristics of the antibodies of Liabeuf.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Myron G. Hill
Patent Examiner
July 11, 2003


JAMES HOUSEL 7/14/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600